

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

CADENCE PHARMACEUTICALS, INC. and
SCR PHARMATOP,

Plaintiffs,

V.

PADDOCK LABORATORIES, INC., PERRIGO COMPANY, PADDOCK LABORATORIES, LLC, EXELA PHARMA SCIENCES, LLC, EXELA PHARMSCI, INC., and EXELA HOLDINGS, INC.,

Defendants.

C.A. No. 11-733-LPS

PUBLIC VERSION

**OPENING BRIEF IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS FOR
LACK OF STANDING OR ALTERNATIVELY, TO ORDER JOINDER
OF BRISTOL-MEYERS SQUIBB UNDER RULE 19**

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INTRODUCTION

Defendants move to dismiss this case for lack of standing pursuant to Fed. R. Civ. P. 12(b)(1) or, alternatively, for this Court to order joinder of Bristol-Myers Squibb Company (BMS) as a necessary party under Rule 19. Specifically, Plaintiffs do not possess all substantial rights in the patents-in-suit. Plaintiff SCR Pharmatop, the patent owner, licensed the patents to BMS. BMS then sublicensed the patents to plaintiff Cadence but BMS retained substantial rights in the patents, [REDACTED] Therefore, all three parties must be named plaintiffs for the case to proceed. BMS is not a party to this litigation. Accordingly, the case must be dismissed or BMS must be joined.

NATURE AND STAGE OF THE PROCEEDINGS

Plaintiffs sued Defendants for infringement of U.S. Patent Nos. 6,028,222 (the '222 patent) and 6,992,218 (the '218 patent) under 35 U.S.C. § 271(e)(2), the Hatch-Waxman Act, as well as under 35 U.S.C. §§ 271 (a)-(c). The Court has issued a claim construction ruling (D.I. 188.) Fact discovery is presently underway and is scheduled to end November 2, 2012. Trial is scheduled to begin May 20, 2013.

SUMMARY OF THE ARGUMENT

Plaintiffs must possess all substantial rights in the patents-in-suit in order to have standing in this lawsuit. If Plaintiffs do not possess all substantial rights in the patents, the case cannot proceed.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]. Given these rights held by BMS, Pharmatop and Cadence do not hold all substantial rights in the patents. BMS is not a party to the case. Therefore, the case must be dismissed.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Because BMS is a necessary party, the Court must order it to be joined.

FACTS

I. PHARMATOP LICENSES TO BMS

Plaintiff SCR Pharmatop is the owner of the '222 and '218 patents, which are directed to allegedly new liquid acetaminophen formulations and methods of making them, respectively.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

¹ Declaration of Edward J. Pardon, filed concurrently. Further references to "Ex." in this brief are to exhibits attached to this declaration.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

II. BMS SUBLICENSES TO CADENCE

[REDACTED] BMS sublicensed certain of its rights to Cadence (the “BMS/Cadence Agreement”) (Ex. B). [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

² [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

3 [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

III. PLAINTIFFS SUE DEFENDANTS WITHOUT BMS

[REDACTED]

[REDACTED] Pharmatop and Cadence

subsequently filed this suit without naming BMS as a party.

ARGUMENT

I. PLAINTIFFS LACK STANDING BECAUSE THEY DO NOT HOLD “ALL SUBSTANTIAL RIGHTS” IN THE PATENTS

Standing to bring a patent suit is a question of subject matter jurisdiction that can be addressed at any point during a lawsuit. *Mentor H/S, Inc. v. Medical Device Alliance, Inc.*, 240 F.3d 1016, 1018 (Fed. Cir. 2001). Plaintiffs bear the burden of proving that subject matter jurisdiction exists. *Cephalon, Inc. v. Watson Pharm.*, 629 F. Supp. 2d 338, 345 (D. Del. 2009). Standing cannot be inferred argumentatively from averments in the pleadings but must affirmatively appear in the record. *Pfizer Inc. v. Elan Pharm. Research Corp.*, 812 F. Supp. 1352, 1356 (D. Del. 1993); *see also Mentor*, 240 F.3d at 1017 (“The party asserting that it has all substantial rights in the patent ‘must produce . . . written instruments documenting the transfer of proprietary rights.’”).

A. Plaintiffs Must Possess All Substantial Rights in the Patents to Have Standing

Only a patentee or permitted exclusive licensees can bring an action for patent infringement. *See Mentor*, 240 F.3d at 1017-18; 35 U.S.C. § 281. Exclusive licensees may bring suit in their own name only if the patentee has granted a license under such terms that are

tantamount to an assignment of the patent, such that the exclusive licensee holds “all substantial rights” in the patent. *Alfred E. Mann Found. for Scientific Research v. Cochlear Corp.*, 604 F.3d 1354, 1359 (Fed. Cir. 2010); *Mentor*, 240 F.3d at 1017; *see also Abbott Labs. Inc. v. Diamedix Corp.*, 47 F.3d 1128, 1131-32 (Fed. Cir. 1995) (licensee did not have standing to sue without licensor where licensor retained “substantial rights” in the patent), *citing Waterman v. Mackenzie*, 138 U.S. 252 (1891) and *Ind. Wireless Tel. Co. v. Radio Corp. of Am.*, 269 U.S. 459 (1926)).

A patent is a “bundle of rights” which may be divided among multiple parties or retained by a single party. *See Alfred E. Mann Found.*, 604 F.3d at 1360. “When a plaintiff lacking a sufficiently large portion of rights brings suit, that plaintiff does not have standing to sue on his own, and the suit must be dismissed, or additional holders of rights under the patent must be joined as parties to the suit[.]” *Id.* This rule is well-established. *See, e.g., Mentor*, 240 F.3d at 1017-18 (“the rule that an exclusive licensee who does not have all substantial rights in a patent must join the patent owner is derived from the statute that defines what parties have standing to sue for patent infringement”); *Abbott*, 47 F.3d at 1131-32 (Fed. Cir. 1995)(noting that an exclusive licensee without sufficient rights must join patent owner); *Intellectual Prop. Dev., Inc. v. TCI Cablevision of Cal., Inc.* 248 F.3d 1333, 1347-1348 (Fed. Cir. 2001) (same).

The primary reason courts require that all substantial rights-holders be joined in the suit is straightforward: it enables the alleged infringer “to respond in one action to all claims of infringement for his act” and thus not be subject to potentially multiple lawsuits from different parties for the same action. *Ind. Wireless*, 269 U.S. at 468, *see also Abbott*, 47 F.3d at 1131; *Aspex Eyewear, Inc. v. Miracle Optics, Inc.*, 434 F.3d 1336, 1343 (Fed. Cir. 2006). Although the case law addressing whether all substantial rights have been transferred deals primarily with the

B.

⁴ The cases typically analyze the question of whether a party holds “all substantial rights” by comparing the rights of two parties – a licensor and a licensee – one of whom is present in the case, and one of whom is absent. Although this case involves three parties, the guiding principle is the same: whether the parties present in the case possess “all substantial rights” *vis-a-vis* the absent party.

⁵ Also critical is that the right be exclusive, which is not at issue in this motion. *Alfred E. Mann Found.*, 604 F.3d at 1360.

[illegible]

c.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED]

⁶ [REDACTED]

D. Other Important Rights Retained by BMS Demonstrate that Plaintiffs Do Not Hold All Substantial Rights in the Patents

Several additional terms in the BMS/Cadence Agreement demonstrate that BMS retained substantial rights typically associated with parties that must be present in a case for standing to exist. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] The fact that BMS has retained all of these rights further demonstrates that neither Cadence nor Pharmatop holds all substantial rights in the patents.

E. The Case Should be Dismissed Because Plaintiffs Lack Standing

Because Pharmatop and Cadence do not hold all substantial rights in the patents-in-suit, they lack standing. When the plaintiff who brings suit lacks standing, the case should be dismissed. *Textile Prods., Inc. v. Mead Corp.*, 134 F.3d 1481, 1485 (Fed. Cir. 1998).

II. ALTERNATIVELY, BMS IS A NECESSARY PARTY UNDER RULE 19 AND MUST BE JOINED

Alternatively, BMS is a necessary party and the Court should order that BMS be made a party under Fed. R. Civ. P. 19. The analysis under Rule 19 is substantially similar to the standing analysis above. *See Abbott*, 47 F.3d at 1133 (noting that the statutory standing analysis is consistent with the policies underlying Rule 19).

Rule 19(a)(1) provides that a party who can be joined as a party should be joined if (A) the party's absence would make it impossible to grant complete relief to the parties, or (B) the missing party claims an interest in the subject matter of the action and is so situated that the disposition of the action in the missing party's absence could impede his ability to protect that interest or leave any of the parties subject to a substantial risk of incurring multiple or inconsistent obligations.⁷ Here, BMS retains an interest in the patents, [REDACTED]

[REDACTED]

[REDACTED]

⁷ The actual text of Rule 19(a)(1) and (2) provides:

(1) *Required Party*. A person who is subject to service of process and whose joinder will not deprive the court of subject-matter jurisdiction must be joined as a party if:

(A) in that person's absence, the court cannot accord complete relief among existing parties; or

(B) that person claims an interest relating to the subject of the action and is so situated that disposing of the action in the person's absence may:

(i) as a practical matter impair or impede the person's ability to protect the interest; or

(ii) leave an existing party subject to a substantial risk of incurring double, multiple, or otherwise inconsistent obligations because of the interest.

(2) *Joinder by Court Order*. If a person has not been joined as required, the court must order that the person be made a party. A person who refuses to join as a plaintiff may be made either a defendant or, in a proper case, an involuntary plaintiff.

Accordingly, BMS is a necessary party. *See Abbott*, 47 F.3d at 1133.

Because BMS is a necessary party, it must be joined. Fed. R. Civ. P. 19(a)(2). BMS is a Delaware Corp⁸ and is therefore properly subject to personal jurisdiction in this Court.

Accordingly, if BMS refuses to join, the Court should join it as a defendant. *See Abbott*, 47 F.3d at 1133.

CONCLUSION

For the reasons discussed above, the Court should dismiss this case for lack of standing or, alternatively, declare that BMS is a necessary party and order that it be joined as a plaintiff (or as a defendant if it refuses to join voluntarily).

Respectfully submitted,

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⁸ See Ex. A at intro (PHARM REV0003272); Ex. B at intro (CADX-1447183).

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CERTIFICATE OF SERVICE

I, David E. Moore, hereby certify that on October 4, 2012, the attached document was electronically filed with the Clerk of the Court using CM/ECF which will send notification to the registered attorney(s) of record that the document has been filed and is available for viewing and downloading.

I further certify that on October 4, 2012, the attached document was Electronically Mailed to the following person(s):

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